## REMARKS

Claims 1-7 are pending. By this Amendment, claims 1 and 7 have been amended to incorporate the chemical structure depicted in the specification in the paragraph following the subheading "Background of the Invention." This chemical structure was amended in the Amendment file June 26, 2009 and the amended chemical structure has been incorporated into claims 1 and 7.

Status of the Patent Claims

Claim 1 is amended by inserting the chemical formula for azithromycin shown in the specification in the paragraph following the subheading "Background of the Invention" as amended in the Amendment file June 26, 2009. Claim 1 was previously amended by inserting "wherein the ethanolate is less hygroscopic than azithromycin monohydrate."

Claims 2-5 have not been amended.

Claim 6 was previously amended by replacing "about 1.5% and about 2.5%" with "about 2.5% and about 3.5%." Claim 6 is not further amended.

Claim 7 is amended by inserting the chemical formula for azithromycin shown in the specification. Claim 7 was previously amended by inserting "wherein the ethanolate is less hygroscopic than azithromycin monohydrate."

Claims 8-15 have been canceled.

Consent of assignee

The application was objected to as lacking the written consent of all assignees holding an undivided interest in the patent. The Office Action stated that the present application lacks the consent of all assignees and that such consent could be demonstrated by filing a PTO/SB/53 form. See the Office Action, page 2, lines 1-6:

> This application is objected to under 37 CFR 1.172(a) as lacking the written consent of all assignees owning an undivided interest in the patent. The consent of the assignee must be in compliance with 37 CFR 1.172. See MPEP § 1410.01.
>
> A proper assent of the assignee in compliance with 37 CFR 1.172 and 3.73 is required in reply to this Office action.
>
> The objection can be overcome by filing a PTO/SB/53 form.

The Applicants respectfully submit that the present application already contains the consent of all assignees because a PTO/SB/53 form with the signatures of representatives of Teva Pharmaceutical Industries Ltd. has already been filed in this application. See Exhibit A (copy of PTO/SB/53 form filed 6 July 2005).

It may be that the Examiner has checked the PTO/SB/53 form shown in Exhibit A against the assignment records of the USPTO for U.S. Patent No. 6,365,574, the parent patent of this reissue application. The assignment records of the USPTO list not only Teva Pharmaceutical Industries Ltd. but also Teva Pharmaceuticals USA, Inc. as assignees (see Exhibit B, copy of assignment records from the USPTO website).

However, Teva Pharmaceuticals USA, Inc. is the assignee of rights in the invention which formed the basis for the present application only for Barbados (see Exhibit C, copy of assignment from Teva Pharmaceutical Industries Ltd. to Teva Pharmaceuticals USA, Inc.). Thus, Teva Pharmaceutical Industries Ltd. is the only assignee of this U.S. reissue application since Teva Pharmaceutical Industries Ltd. owns all rights to U.S. Patent No. 6,365,574. Therefore, the PTO/SB/53 form that has already been filed in this reissue application is correct and indicates that this reissue application already contains the consent of all assignees.

Accordingly, it is respectfully requested that this objection be withdrawn.

Reissue Declaration

Claims 1-7 were rejected as being based on a defective reissue declaration. The Office Action stated that the reissue declaration is defective because of the amendment to claims 1 and 7 made in the Amendment filed June 26, 2009. See the Office Action, page 2, lines 7-16:

> The reissue oath/declaration filed with this application is defective because the error which is relied upon to support the reissue application is not an error upon which a reissue can be based. See 37 CFR 1.175(a)(1) and MPEP § 1414.
>
> In the declaration filed 11/16/2005, the error upon which reissue is based is stated as "Claims 1, 6, and 7 were amended to recite that the claimed ethanolate of azithromycin is non-hygroscopic to more fully distinguish over US 4,475,768 to Bright which discloses a hygroscopic azithromycin compound". However, note that in the claims filed on 6/26/2009, claims 1 and 7 were amended as being directed to an ethanolate of azithromycin "wherein the ethanolate is less hygroscopic than azithromycin monohydrate".

The Supplemental Reissue Declaration filed 16 November 2005 for this reissue application gave the following reason as the error that justified reissue:

> Claims 1, 6 and 7 were amended to recite that the claimed ethanolate of azithromycin is non-hygroscopic to more fully distinguish over US 4,474,768 to Bright which discloses a hygroscopic azithromycin compound

In the Amendment filed June 26, 2009, the claims were amended to delete the phrase "non-hygroscopic" and replace that phrase with the phrase "less hygroscopic than azithromycin monohydrate." Apparently, the Examiner has taken the position that because the claims no longer recite "non-hygroscopic" the error referred to in the Supplemental Reissue Declaration filed November 16, 2005 no longer applies and therefore the Supplemental Reissue Declaration is no longer acceptable.

However, in the context of this reissue application, the phrase "less hygroscopic than azithromycin monohydrate" means the same thing as "non-hygroscopic." See the last Amendment, filed 26 June 2009, where it was explained that:

> Claims 1 and 7 are amended to recite, *inter alia*, "wherein the ethanolate is less hygroscopic than azithromycin monohydrate." Literal support for the amendments to the claims can be found at, for example, page 2, lines 11-13, of the specification. Page 2, lines 11-13, of the specification discloses "a new ethanolate of azithromycin that is less hygroscopic than azithromycin monohydrate." This amendment is made for purposes of clarification only and does not narrow the scope of the claim. In the Interference proceedings related to this application, the Director considered the meaning of "non-hygroscopic" as applied in the specification of U.S. Patent No. 6,365,574 (the parent patent of Reissue Application No. 10/816,376). In the November 8, 2006 Memorandum Opinion and Order, the Director stated "When [U.S. Patent No. 6,365,574] is considered as a whole, we find that "non-hygroscopic" means "less hygroscopic than azithromycin monohydrate." (Page 42, lines. 10-11) (emphasis added). In light of the disclosures in the specification, it would be apparent to one skilled in the art that "non-hygroscopic" means "less hygroscopic than azithromycin monohydrate."

Thus, the Trial Section of the Board of Patent Appeal and Interferences has found that the phrase "less hygroscopic than azithromycin monohydrate" means the same thing as "non-hygroscopic" in this application. Therefore, the amendments to claims 1 and 7 made in the Amendment filed June 26, 2009 did not change the subject matter of claims 1 and 7.

If the subject matter of the claims has not changed, then the error stated in the Supplemental Reissue Declaration still applies since the claims still more fully distinguish over the Bright patent. Thus, the Applicants respectfully submit that the Supplemental Reissue Declaration is still acceptable.

Accordingly, it is respectfully requested that this rejection be withdrawn

Chemical structure of azithromycin

The Office Action objected to the specification because the chemical structure in the specification is "not the same as the one the applicant has placed in the registry file of chemical abstracts. See Office Action, page 3, lines 1-6:

> The disclosure is objected to because of the following informalities: the specification is objected to for having a formula not the same as the one the applicant has put in as the ethanolate in the registry file of chemical abstracts.
>
> For example, note that in the structure set forth in the registry, the sugars at positions 3 and 5 are attached by solid lines while in the structure set forth in the specification, said sugars are attached by the dashed lines.

The Applicants respectfully submit that this objection is in error. An applicant may describe the invention in any manner the applicant sees fit. There is no requirement that an applicant conform the description of the invention in the specification to a disclosure in the scientific literature. The Office Action also erred by stating that the applicant has put in the chemical structure of the azithromycin ethanolate in the Registry File of Chemical Abstracts because the chemical structure shown in the Registry File was placed in the Registry File by the Chemical Abstracts Service, not the applicant. Accordingly, it is respectfully requested that this objection be withdrawn.

Indefiniteness rejection

Claims 1-7 were rejected under 35 U.S.C. §112, second paragraph, for indefiniteness. According to the Office Action, it is unclear whether the compound being claimed is the compound shown in the specification or the compound shown in the registry number of chemical abstracts. See the Office Action, page 3, lines 11-16:

> Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
>
> Claims 1-7 directed to the compound of ethanolate are vague and indefinite as to whether the compound being claimed is the compound found in the specification or the compound found in the registry number given by applicant as his ethanolate.

The Examiner's position apparently is that there would be confusion about what is being claimed because there is a difference between what is disclosed in the specification and what is disclosed in chemical abstracts. This position is incorrect; case law makes it clear that what is disclosed in the specification controls. A claim is indefinite only if one skilled in the art would not understand what is claimed when the claim is read in light of the specification. *See Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F. 2d 1565, 1576, 1 U.S.P.Q. 2d 1081, 1088 (Fed. Cir. 1986): "A decision on whether a claim is invalid under § 112, 2d ¶, requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification." *See also Phillips v. AWH Corporation*, 415 F.3d 1303, 1317, 75 U.S.P.Q. 2d 1321, 1329

(Fed. Cir. 2005), which states that the specification is the "single best guide" to claim construction.

One of skill in the art would not first turn to File Registry of Chemical Abstracts to interpret the claims; instead one of skill in the art would first turn to the specification. When one of skill in the art finds the chemical structure of the azithromycin ethanolate disclosed in the specification, he/she would not consult File Registry of Chemical Abstracts for the structure of azithromycin ethanolate. Thus, there would be no doubt in the mind of one of skill in the art which structure is recited in the claims – it is the structure in the specification.

Nevertheless, in the interest of expediting prosecution, claims 1 and 7 have been amended to insert the structure that is disclosed in the specification.

The recitation of "substantially" in claim 7

Claim 7 was rejected under 35 U.S.C. §112, second paragraph, for indefiniteness because of the recitation of the term "substantially." The Office Action stated, at page 3, lines 17-21:

> Claim 7 is directed to an ethanolate of azithromycin that is characterized by a powder x-ray diffraction substantially as depicted in Fig.2. There is no presence or definition of the term "substantially" in the specification. Therefore, the term "substantially" is vague and indefinite as to what the metes and bounds that applicant considers his invention since it is a relative term.

The Applicants respectfully traverse this rejection. In the right context, courts have approved of the use of the word "substantially" in claims, even without an explicit definition in the corresponding specification. For example, the issue of whether the term "substantially" is indefinite absent a definition in the specification was addressed by the Federal Circuit in *Verve, LLC v. Crane Cams, Inc.*, 311 F. 3d 1116, 65 U.S.P.Q. 1051 (Fed. Cir. 2002). In *Verve*, the district court found that the expression "substantially constant wall thickness" rendered the claims indefinite because the specification and prosecution history did not provide a sufficiently clear definition of "substantially." The Federal Circuit overruled the district court, stating:

> Expressions such as "substantially" are used in patent documents when warranted by the nature of the invention, in order to accommodate the minor variations that may be appropriate to secure the invention. Such usage may well satisfy the charge to "particularly point out and distinctly claim" the invention, 35 USC §112, and indeed may be necessary in order to provide the inventor with the benefit of his invention. *In Andrew Corp. v. Gabriel Elecs. Inc.*, 847 F.2d 819, 821-22, 6 USPQ2d 2010, 2013 (Fed. Cir. 1988), the court explained that usages such as "substantially equal" and "closely approximate" may serve to describe the invention with precision appropriate to the technology and without intruding on the prior art. The court again explained in *Ecolab Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367, 60 USPQ2d 1173, 1179 (Fed. Cir. 2001) that "like the term 'about,' the term 'substantially' is a descriptive term commonly used in patent claims to 'avoid a strict numerical boundary to the specified parameter,'" quoting *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217, 36 USPQ2d 1225, 1229 (Fed. Cir. 1995). *Verve, LLC v. Crane, Id* at 1119.

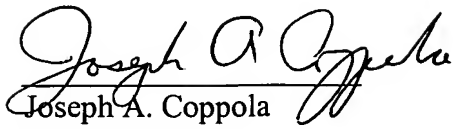
Given the nature of the present invention, one skilled in the art would understand what "substantially" means, even without an explicit definition in the specification. In claim 7, "substantially" is being used to refer to a PXRD pattern. This seems a particularly appropriate technology for the use of "substantially" since use of "substantially" in this context ensures that the Applicants receive the protection they are due; it would be unfair if an infringer were able to avoid claim 7 because PXRD measurements of that infringer's azithromycin ethanolate differed in a trivial manner from the results shown in Figure 2 merely due to the unavoidable uncertainties associated with any PXRD measurement. Thus, the word "substantially" in claim 7 is being used in order to "describe the invention with precision appropriate to the technology" and to "provide the inventor with the benefit of his invention," two uses that were specifically approved by the *Verve* court.

The time for responding to the Office Action was set for December 30, 2009. Therefore, it is believed that this response is timely. If this is in error, please treat this response as containing a Petition for the Extension of Time under 37 C.F.R. § 1.136(a) for a period sufficient to permit the filing of this paper and charge any corresponding fees to Kenyon & Kenyon's Deposit Account No. 11-0600.

The Applicants hereby make a Conditional Petition for any relief available to correct any defect seen in connection with the filing of this paper, or any defect seen to be remaining in this application after the filing of this paper. The Commissioner is authorized to charge Kenyon & Kenyon LLP's Deposit Account No. 11-0600 for the Petition fee and any other fees required to effect this Conditional Petition.

Respectfully submitted,

Dated: 12/21/09

BY: 

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# EXHIBIT A

PTO/SB/53 (05-03)
Approved for use through 01/31/2004. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| REISSUE APPLICATION: CONSENT OF ASSIGNEE; STATEMENT OF NON-ASSIGNMENT | Docket Number (Optional) 1662/492021 |
|---|---|

This is part of the application for a reissue patent based on the original patent identified below.

Name of Patentee(s)

Claude Singer and Judith Aronhime

| Patent Number 6,365,574 B2 | Date Patent Issued April 2, 2002 |
|---|---|

Title of Invention EHTANOLATE OF AZITHROMYCIN, PROCESS FOR MANUFACTURE, AND PHARMACEUTICAL COMPOSITIONS

1. ☒ Filed herein is a certificate under 37 CFR 3.73(b). (Form PTO/SB/96)

2. ☐ Ownership of the patent is in the inventor(s), and no assignment of the patent has been made.

One of boxes 1 or 2 above must be checked. If multiple assignees, complete this form for each assignee. If box 2 is checked, skip the next entry and go directly to "Name of Assignee".

The written consent of all assignees and inventors owning an undivided interest in the original patent is included in this application for reissue.

The assignee owning an undivided interest in said original patent is/are **Teva Pharmaceutical Industries, Ltd.** and the assignee(s) consents to the accompanying application for reissue.

Name of assignee/inventor (if not assigned)

**Teva Pharmaceutical Industries, Ltd.**

| Signature X | Date X 10/6/2005 |
|---|---|

Typed or printed name and title of person signing for assignee (if assigned)

**Yehudah Livneh, PhD, General Patent Counsel**

| Signature X | Date X 19.8.05 |
|---|---|

Typed or printed name and title of person signing for assignee (if assigned)

**Uzi Kamiel, General Counsel and Corporate Secretary**

# EXHIBIT B

## Assignments on the Web > Patent Query

# Patent Assignment Abstract of Title

***NOTE:Results display only for issued patents and published applications. For pending or abandoned applications please consult USPTO staff.***

**Total Assignments: 2**

**Patent #:** 6365574 **Issue Dt:** 04/02/2002 **Application #:** 09451738 **Filing Dt:** 11/30/1999

**Publication #:** 20020007049 **Pub Dt:** 01/17/2002

**Inventors:** CLAUDE SINGER, JUDITH ARONHEIM

**Title:** ETHANOLATE OF AZITHROMYCIN, PROCESS FOR MANUFACTURE, AND PHARMACEUTICAL COMPOSITIONS THEREOF

**Assignment: 1**

**Reel/Frame:** 010675/0559 **Recorded:** 04/05/2000 **Pages:** 3

**Conveyance:** ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

**Assignors:** SINGER, CLAUDE **Exec Dt:** 02/09/2000

ARONHIME, JUDITH **Exec Dt:** 02/09/2000

**Assignee:** TEVA PHARMACEUTICALS INDUSTRIES LTD.
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**Correspondent:** KENYON & KENYON
PAMELA G. SALKELD
ONE BROADWAY
NEW YORK, NEW YORK 10004

**Assignment: 2**

**Reel/Frame:** 010674/0443 **Recorded:** 04/05/2000 **Pages:** 2

**Conveyance:** ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

**Assignor:** TEVA PHARMACEUTICAL INDUSTRIES, LTD. **Exec Dt:** 02/10/2000

**Assignee:** TEVA PHARMACEUTICALS USA, INC.
1510 DELP DRIVE
KULPSVILLE, PENNSYLVANIA 19443

**Correspondent:** KENYON & KENYON
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Web interface last modified: October 18, 2008 v.2.0.2

# EXHIBIT C

1662/49202

# ASSIGNMENT

WHEREAS **TEVA PHARMACEUTICAL INDUSTRIES LTD.**, having a place of business at **5 Basel Street, P.O. Box 3190, Petah Tiqva 49131, Israel**, hereinafter called "Assignor," is the owner of the entire right, title, and interest in and to inventions and discoveries in a **ETHANOLATE OF AZITHROMYCIN, PROCESS FOR MANUFACTURE, AND PHARMACEUTICAL COMPOSITIONS THEREOF** (hereinafter, "the Invention"), described in **U.S. Patent Application Serial No. 09/451,738, filed on November 30, 1999**, and

WHEREAS **TEVA PHARMACEUTICALS USA, INC.**, having a place of business at **1510 Delp Drive, Kulpsville, Pennsylvania 19443, United States of America**, hereinafter called "Assignee," is desirous of acquiring the title, rights, benefits, and privileges hereinafter recited,

NOW, THEREFORE, for good and valuable consideration furnished by Assignee, receipt and sufficiency of which is hereby acknowledged, Assignor hereby, without reservations,

1. Assigns, transfers, and conveys to Assignee the entire right, title, and interest in and to the Invention in, and only in, the nation and territory of **Barbados**, and in and to any **Barbados** national patent that may issue for the Invention; and

2. Authorizes Assignee to file, under the International Convention or otherwise, for patent protection for the Invention within the nation and territory of **Barbados**.

**TEVA PHARMACEUTICAL INDUSTRIES LTD.**

Signature: [signature]

Date: Feb 10, 2000

Name of Person Signing: Yehudah Livneh

Title of Person Signing: Director of Patents

Signature: M. Mann

Date: 5 March 2000

Name of Person Signing: Meron Mann

Title of Person Signing: V.P. Chemicals

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